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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/807,403

07/02/2001

Kenneth William Hunt

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05/28/2008

KINETIC CONCEPTS, INC.

ATTN: LEGAL DEPARTMENT INTELLECTUAL PROPERTY

P.O. BOX 659508

SAN ANTONIO, TX 78265

EXAMINER

HAND, MELANIE JO

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/807,403	Applicant(s) HUNT ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection. However examiner will address the essence of applicant's arguments herein. As to applicant's request that the application be made special, statement to this effect in an amendment is not the proper protocol for making a non-provisional application special. In order to expedite response from the examiner, which is what applicant appears to be requesting, applicant must file a "Petition to Make Special" as described in MPEP 708.02. This application was forwarded to examiner and examiner has responded within the 2-month standard time period, therefore it does not appear that the application is in the status that applicant is requesting. Applicant is also reminded that the current examiner is not the original examiner, and the time period of greater than five years is beyond the current examiner's control. Applicant's argument 1A that Lina fails to teach or suggest a shut-off valve which closes an outlet from the collection canister in response to the canister being full. This argument is based upon an amendment to claim 1. While applicant is correct, and this amendment prompted the withdrawal of the rejection of claims 1-15 under 35 U.S.C. 103 as unpatentable over Lina, the closest prior art of record, applicant's disclosure as originally filed is of a scope that does not fully enable this limitation. The disclosure does state that the shut-off valve is shut off automatically when the canister is full, but does not describe at all how this is accomplished. Therefore, claims 1-15 are herein rejected under 35 U.S.C. 112, first paragraph. As to applicant's argument 1B, Lina certainly suggest a tube connecting to a wall suction point. the fact that the Lina device is portable in no way precludes or teaches away from it from being used in a stationary capacity, e.g. adjacent a hospital bed. The device of Lina simply has the

advantage of having its own suction pump therein for portability when needed or desired. The fact that wall is not mentioned is immaterial. The instant device is a wound drainage device, and wounds are commonly drained in enclosed sterile environments (e.g. hospitals) having walls. One of ordinary skill in the art would certainly be motivated to use the instant wound drainage device in a hospital or clinic environment having walls and wall suction points. As to argument 1C, that argument is also persuasive and has at least in part prompted the withdrawal of the rejection of claim 1 under 35 U.S.C. 103. As to argument section II, pages 17 and 18 appear to be simply a repetition of case law regarding obviousness with no substantive argument. Applicant argues on page 19 that Lina already achieves all of the advantages of the claimed invention and thus there would be no motivation to modify the device of Lina to permit hanging the apparatus from a foot board. Examiner has reviewed the previous Office action mailed November 14, 2007 several times and not found this statement, therefore the argument will not be addressed. As to argument III, this argument is derived from applicant's argument that it would not be obvious to use the device of Lina with a wall suction point, which examiner has addressed *supra*. As to argument IV, this argument is derived from applicant's argument that Lina does not teach a shut-off valve that closes an outlet to the instant canister in response to the canister being full. This argument has also been addressed *supra*.

2. Applicant does not appear to argue claims 14 and 15. This failure to address the rejection of claims 14 and 15 is regarded as a concession that the rejections are proper and are thus maintained herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a shut-off valve that automatically closes the outlet from the canister when the canister is full (Specification, Page 4, lines 8-10), does not reasonably provide enablement for any structural features or processes which are responsible for this automatic closure of the shut-off valve in response to the canister being full. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant states on page 4 of the specification that the canister may be of conventional design having a shut-off valve which automatically closes once the canister is full. The conventional design is interpreted herein by examiner to refer to only the structure of the canister, which includes the shut-off valve, as such shut-off valves are conventional in the wound canister art. However, a shut-off valve must either be operated manually or automatically by an external input to convert from the open state to the closed state, such as manual force by a human operator or automated mechanical structure, or an electronic signal from an external control. An automatic shut-off valve is not conventional, and there is no further description of the valve or the manner in which this automatic closure in response to the canister being full in the disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

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ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al (WO 96/05873 A1).

With respect to **claim 14**: Lina teaches an apparatus for applying negative pressure therapy to a wound site, the apparatus comprising: an open-celled foam pad 36 for application to the wound site; a suction tube in the collective form of hoses 37,38 connecting the foam pad 36 to a collection canister 19; a pressure regulator in the form of restrictor 89 fluidly connected between the canister 19 and vacuum pump 84; and a processor in the form of microcontroller 72 in electronic communication with the pressure regulator 89 to regulate the pressure from said vacuum pump 84 to the collection canister 19.

Lina does not explicitly teach a wall suction source, however a wall suction source is an example of a vacuum pump and performs a substantially identical function to the vacuum pump taught by Lina. Thus, it would be obvious to one of ordinary skill in the art to substitute a wall suction source for the vacuum pump taught by Lina with a reasonable expectation of success to ensure that the suction function of the instant apparatus is preserved while the device is

stationary or when the device is used portably with the instant vacuum pump. (Page 7, ¶3, Page 17, ¶¶ 2,3)

With respect to **claim 15**: The pressure regulator includes a relief valve in the form of bleed valve 86 along tube 62, and wherein the processor 72 is configured to actuate the relief valve 86 to relieve pressure in tube 62, which, due to the action of restrictor 89 as described with respect to claim 12 *supra* is equal to pressure at the wound site, when pressure at the wound site reaches a set maximum pressure. (Page 16, ¶3, Page 17, ¶3)

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761